

REMARKS

Reconsideration of the captioned application as amended herewith is respectfully requested.

This Response is filed concurrently with a petition for a **one (1) month extension of time** to respond to the Office Action, which will extend the period of response from 29 September 2007 to 29 October 2007.

The Office Action:

- (a) made final the restriction requirement and withdrew claims 14 – 41 from consideration;
- (b) provisionally rejected claims 1 – 13 under 35 USC §101 as allegedly claiming the same invention as that of claims 1 – 13 in copending Application No. 10/797,367;
- (c) provisionally rejected claims 1 – 13 on the basis of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1 – 13 of copending Application No. 10/780,452 in view of Chandrasekar, et al., "Platelets and Restenosis," 35(2) JI. American College of Cardiology 555-562 (2000)("Chandrasekar") and Miyazawa, et al., "Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat" 30(2) JI. Cardiovascular Pharmacology (Aug. 1997 abstract) ("Miyazawa");
- (d) rejected claims 1 – 5 and 7 – 13 under 35 USC §102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Adachi, et al., "The Prevention of Postoperative Intrapitoneal Adhesions by Tranilast" N-(3',4'-dimethoxycinnanoyl) Anthranilic Acid" ("Adachi");
- (e) rejected claims 1 - 13 under 35 USC §103(a) as obvious over Adachi in view of United States Patent No. 6,376,242 to Hanson ("Hanson").

Claims 14 – 41 were withdrawn. Claims 1 – 13 remain pending in this application after entry of this response.

Applicants respectfully submit that (1) the provisional rejection of claims 1 – 13 under 35 USC §101 as allegedly claiming the same invention as that of claims 1 – 13 in copending Application No. 10/797,367; and (2) the provisional rejection of claims 1 – 13 on the basis of nonstatutory obviousness-type double patenting over claims 1 – 13 of copending Application No. 10/780,452 in view of Chandrasekar and Miyazawa, are moot in view of the fact that the subject

matter in the above-referenced application, and in copending Application Nos. 10/797,367 or 10/780,452, has not issued into a patent.

1. The Rejection of Claims 1 – 5 and 7 - 13 under 35 USC §102(b) or alternatively 35 USC §103(a) over Adachi Should Be Withdrawn

Claims 1 – 5 and 7 - 13 stand rejected under 35 USC §102(b) as allegedly being anticipated by Adachi, or alternatively claims 1 – 5 and 7 - 13 stand rejected under 35 USC §103(a) as allegedly being unpatentable over Adachi. Applicants respectfully disagree for the reasons that follow.

Adachi discloses an adhesion study model wherein "Tranilast was administered orally pre- and postoperatively," and "the effects of tranilast... on adhesion formation" were then studied. See Adachi, page 1 abstract and page 1 column 2 (emphasis added).

As expressly provided in the Office Action, "Adachi does not specifically state that the tranilast is administered directly to tissue surfaces of the body" (emphasis added). By contrast, independent claim 1 is directed to a "method for the inhibition of post-operative adhesion formation in a body... comprising administering Tranilast... directly to said tissue surfaces in said body cavity" (emphasis added).

Rejections under 35 USC §102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. In re Marshall, 198 USPQ 344 (CCPA 1978). In other words, to constitute an anticipation, all material elements recited in a claim must be found in one unit of prior art. Id. The exclusion of a claimed element from a prior art reference is enough to negate anticipation under 35 USC §102 by that reference. Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 224 USPQ 409 (Fed. Cir. 1984).

Therefore, since Adachi fails to disclose or suggest at least one element of Applicants' independent claim, i.e., e.g., "administering Tranilast ... directly to said tissue surfaces in said body cavity" as claimed herein, Applicants respectfully submit that the rejection of claim 1, and claims 2 – 13 which dependent therefrom and incorporate all of its limitation therein, under 35 USC §102(b) over Adachi has been overcome and should be withdrawn.

Applicants further respectfully submit that the invention as presently claimed is not obvious over the oral administration of tranilast as disclosed in Adachi. As shown in Example 3 on page 33 of the Specification, Applicants analyzed adhesion formation resulting from either: (a)

the local delivery of tranilast; (b) placebo control; or (c) the oral dosing of tranilast. See Specification, page 33, lines 5 – 10. As shown in Tables 12 – 16, there

were reductions in the area of adhesion formation in all groups that received local delivery of Tranilast (Tables 13 and 16). Oral Tranilast alone did not reduce the area of adhesion formation (Tables 14 and 15).

See Specification page 34, lines 12 – 17. This Example clearly showed that "Tranilast was shown to be efficacious when delivered to the site via a local administrative route [; however, when] delivered via a systemic route, no efficacy was seen. Hence, only local delivery is effective in reducing post-operative adhesions." See Specification, page 37, lines 5 – 10.

Thus, not only does Adachi fail to disclose or suggest elements of the present invention, "administering Tranilast ... directly to said tissue surfaces in said body cavity" (emphasis added), Applicants further respectfully submit that such a method of administration resulted in an unexpectedly significant reduction in adhesion formation in comparison to the amount of adhesion formation resulting from oral administration as disclosed in Adachi. Therefore independent claim 1, as well as claims 2 – 5 and 7 – 13 dependent upon claim 1, are patentable over Adachi, and the rejection of these claims under 35 USC §103(a) should be withdrawn.

2. The Rejection of Claims 1 – 13 under 35 USC §103(a) over Adachi in view of Hanson Should Be Withdrawn

Claims 1 - 13 stand rejected under 35 USC §103(a) as being unpatentable over Adachi in view of Hanson. Applicants respectfully disagree for the reasons that follow.

Applicants respectfully submit that the claims are patentable over Adachi for the reasons set forth above in Section 1. The Office Action has failed to point out where Hanson discloses or suggests "administering Tranilast ... directly to said tissue surfaces in said body cavity" (emphasis added). Therefore independent claim 1, as well as claims 2 - 13 dependent upon claim 1, are patentable over the combination of Adachi with Hanson, and the rejection of these claims under 35 USC §103(a) should be withdrawn.

3. Conclusion

It is submitted that the foregoing remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

Respectfully submitted,

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